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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,608	01/14/2002	Leonard Bell	59	5748

7590 06/03/2005

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,608	BELL, LEONARD	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/262,540.

Claims 1-26 have been canceled.

New claims 27-41 have been added and are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The previously pending claims have been replaced in an attempt to differentiate the claimed invention form the prior art of record. New claim 27 recites that the method comprises a first step of administering an anti-inflammatory agent prior to or at the start of surgery and a second step of administering an anti-inflammatory agent subsequent to the start of surgery. Claim 36 recites that the method comprises a single step of administering an anti-inflammatory agent prior to or at the start of surgery. However, the aforementioned limitations of new base claims 27 and 36 are not disclosed in the specification or claims as originally filed and constitute new matter. The specification discloses at page 1, lines 4-6, "[m]ethods of prophylaxis against myocardial infarctions which exhibit CK-MB levels greater than about 50 nano-grams/ml in a subject are also described" and in the sentence bridging pages 3-4, "[i]t

would be of further advantage to provide a method of prophylaxis against large myocardial infarctions as indicated by peak CK-MB levels of about 50 nano-grams/ml or more." The only other disclosure of the method of prophylaxis is found at page 4, lines 13-17 in the recitation:

> "In another embodiment a method of prophylaxis against myocardial infarctions which exhibit peak CK-MB levels greater than about 50 nano-grams/ml in a subject is provided. This method includes administering to the subject undergoing a prccedure involving cardiopulmonary bypass an effective myocardial infarction reducing amount of an anti-inflammatory compound."

The step(s) for the method were also originally set out in claim 1, as originally filed, which recites:

> "A method of prophylaxis against myocardial infarctions which exhibit CK-MB levels greater than about 50 nano-grams/ml in a subject comprising:
> administering to the subject undergoing a procedure involving cardiopulmonary bypass an effective myocardial infarction reducing amount of an anti-inflammatory compound."

The dependent claims set forth only concentrations and the nature of the anti-inflammatory compounds. Furthermore, the only type of "anti-inflammatory compound" that is adequately set forth in the specification or claims as originally filed is antibodies to complement components or to proteins associated with the complement system. The specification recites at page 7, lines 21-23 that "[a]ny compounds which bind to or otherwise block the generation and/or activity of any of the human complement components, such as, for example, antibodies specific to a human complement component are useful herein." However, the only anti-inflammatory compounds described in the specification are the anti-complement antibodies. The specification makes no additional disclosure of anti-inflammatory compounds, a class of compounds that is quite broad and therefore requires greater disclosure in order to be adequately described. For example, prostaglandin inhibitors is one class of anti-inflammatory compounds, but not even a single example of the class is found in the instant specification.

The specification and claims as originally filed do not specify a particular time point for administering the anti-inflammatory compound, nor do the specification and claims as originally filed specify the administration of "additional" compound as an additional step. Accordingly, the recitation of "administering an anti-inflammatory agent to said patient prior to or simultaneously with the start of said surgery" in claims 27 and 36 and the recitation of "administering additional anti-inflammatory agent subsequent to the start of said surgery" in claim 27 constitute new matter. There is no such direction provided, either direct or implied, in the specification or claims as originally filed.

Additionally, there is no disclosure whatsoever in the specification or claims as originally filed of a time period specifying how long the claimed method will prevent myocardial infarctions. Accordingly, the recitation of "such that said anti-inflammatory agent remains effective in preventing myocardial infarction for at least 24 hours" in claim 36 constitutes new matter.

3. Claims 32 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The hybridoma cell line producing the antibody yielding the humanized single-chain product h5G1.1-scFv required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of *35 U.S.C. 112*, first paragraph, may be satisfied by a deposit of said cell lines. *See 37 C.F.R. 1.802.*

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 C.F.R. 1.808.*

In addition, the identifying information set forth in *37 C.F.R. 1.809 (d)* should be added to the specification. *See 37 C.F.R. 1.803-1.809* for additional explanation of these requirements, Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 C.F.R. 1.801-1.809 for further information concerning deposit practice.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is indefinite and ambiguous to recite the laboratory name "h5G1.1-scFv" in claims 32 and 41 to identify the humanized single-chain antibody. The same designation may likely to be used by others as well to designate different cell lines. It is suggested that the corresponding accession or deposit numbers from an acceptable depository be recited in the claim.

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. FPV
Patent Examiner
May 25, 2005

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182